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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,436	10/28/2003	Matthew F. Schmidt	225.00010124	4462
26813 7590 07/11/2007 MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			EXAMINER MITCHELL, TEENA KAY	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 07/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,436	<b>Applicant(s)</b> SCHMIDT ET AL.	
	<b>Examiner</b> Teena Mitchell	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

  
TEENA MITCHELL  
PRIMARY EXAMINER

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/7/04;3/14/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The request for interference filed 10/28/03 is acknowledged. However, examination of this application has not been completed as required by 37 CFR 41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.

#### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

While the applicant has made a duty to disclose statement the statement is incorrect. Applicant states, "...we hereby acknowledge our duty to disclose to the United States Patent and Trademark Office **all information known to us to be material to the patentability as defined in Title 37, Code of Federal Regulations, 1.56**. Note the correct statement above, applicant uses the words the patentability "the" makes the statement provided incorrect.

#### *Claim Objections*

Claims 46 and 74 are objected to because of the following informalities:

Claim 46, line 10, "...overage..." should be amended to read --average--.

Claim 74, lines 3 and 4, "...between a first position to flow from said supply..." it is unclear as to what is flowing as written it almost appears that the valve flows from. Correction is required.

***Claim Rejections - 35 USC § 112***

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, the pressure sensor is not disclosed in the originally filed specification, thus the newly added limitation would constitute new matter. In claim 4, the pressure sensor comprising a diaphragm exposed to the atmosphere on opposing sides so as to be altitude correcting is not disclosed in the originally filed specification, therefore the limitation would constitute new matter. In claim 5, the limitations of, "...generating information regarding an average flow rate of oxygen delivered from said supply to said user..." and "...determining if a change in average flow rate exceeds a predetermined amount and, if so, triggering an alarm..." is not disclosed in the originally filed specification, therefore the limitations would constitute new matter. In claim 8, "...said predetermined amount comprises a predetermined percentage change in average flow rate..." is not disclosed in the originally filed specification therefore, the limitations would constitute new matter. In claim 9, "...illuminating a light..." is not disclosed in the originally filed specification

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therefore, the limitations would constitute new matter. In claim 10, "...comprises emitting an audible alarm..." is not disclosed in the originally filed specification therefore, the limitations would constitute new matter. In claim 11, "...output from said flow sensor and utilizing the stored information to generate said average flow rate..." the limitations are not disclosed in the originally filed specification therefore the limitations would constitute new matter. In claim 12, "...generating flow rate information with a flow sensor and utilizing said flow rate information to generate information regarding average flow rate..." the limitations are not disclosed in the originally filed specification therefore, the limitations would constitute new matter. In claim 13, "...determining an average dose time, said average dose time indicative of the average flow rate of oxygen delivered to said user and triggering an alarm if said average dose time changes by an amount exceeding a predetermined amount..." the limitations are not disclosed in the originally filed specification therefore, the limitations constitute new matter. In claim 15, "...determining a maximum time said valve should be moved to said first position, determining a minimum time said valve should be moved to said first position, and determining a variable time said valve should be moved to said first position..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 19, "...a linearly changing quantity between a minimum quantity corresponding to said minimum time and maximum quantity corresponding to said maximum time..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 21, "...an average does time calculator..." and "...said processor configured to utilize average does time

information generated by said average dose time calculator...” the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 23, “...audible alarm...” the limitations are not disclosed in the originally filed specification and therefore the limitations constitute new matter. In claim 24, “...visual warning...” is not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 25, “...a printed circuit board located within a housing and said selector comprises a user-actuable input extending from said housing...” the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 26, “...the pressure sensor comprising a diaphragm exposed to the atmosphere on opposing sides so as to be altitude correcting...” the limitations are not disclosed in the originally filed specification therefore constitute new matter. In claim 27, “...generating information regarding an average dose time of oxygen delivered from said supply to said user; and determining if a change in said average dose time exceeds a predetermined amount and, if so, triggering an alarm...” the limitations are not disclosed in the originally filed specification therefore, the limitations constitute new matter. In claim 30, “...alarm comprises illuminating a light...” the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 31, “...emitting an audible noise...” the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 33, “...the sensor including a diaphragm exposed to the atmosphere on opposing sides so as to be altitude correcting and arranged to detect a period of inhalation...” the limitations are not disclosed in the

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originally filed specification therefore the limitations constitute new matter. In claim 35, "...an audible alarm..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 36, "...visual warning..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 37, "...a printed circuit board located within a housing and said selector comprises a user-actuable input extending from said housing..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 38, "...generating at two or more times information regarding an average flow rate of oxygen delivered from said supply to said user; determining if a change in average flow rate exceeds a predetermined amount and, if so, triggering an alarm..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 41, "...a predetermined percentage change in average flow rate..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 42, "...illuminating a light..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 43, "...emitting an audible noise..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 44, "...said output of said flow sensor and utilizing said stored information to generate said average flow rate..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 45, "...generating flow rate information with a flow sensor and utilizing said flow rate information to generate information regarding

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average flow rate..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 46, "...determining an average flow rate of oxygen delivered to said user and triggering an alarm if said average flow rate of oxygen changes by an amount exceeding a predetermined amount..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 48, "...utilizing flow rate data received as an output of a flow sensor to calculate said average flow rate..." the limitations are not disclosed in the specification therefore the limitations constitute new matter. In claim 50, "...determining a first maximum time if said actual level has not reached said goal level or said actual level is below a minimum level, determining a second minimum time if said actual level is above a goal level, and determining a variable time..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 53, "...said desired quantity of oxygen comprises a maximum quantity when said actual level is below said minimum level..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 54, "...a linearly changing quantity between a minimum quantity corresponding to said minimum time and a maximum quantity corresponding to said maximum time..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 56, "...said determined length of time does not exceed one-half of an inhalation time of said user..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 57, "...said sensor including a diaphragm exposed to the atmosphere



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on opposing sides so as to be altitude correcting..." and "...a flow sensor..." and "...configured to utilize flow rate information generated by said flow sensor and trigger an alarm in the event said utilized flow rate information meets a predetermined criteria..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 59, "...audible alarm..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 60, "...visual warning..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 61, "...printed circuit board located within a housing and said selector comprises a user-actuable input extending from said housing..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 62, "...generating at two or more times information regarding an average flow rate of oxygen delivered from said supply to said user; determining if a change in average flow rate exceeds a predetermined amount and, if so, triggering an alarm..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 65, "...said predetermined amount comprises a predetermined percentage change in average flow rate..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 66, "...illuminations a light..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 67, "...emitting an audible noise..." limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 68, "...flow sensor..." the limitations are

not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 69, "...generating flow rate information with a flow sensor and utilizing said flow rate information to generate information regarding average flow rate..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 70, "...determining an average flow rate of oxygen delivered to said user and triggering an alarm if said average flow rate of oxygen changes by an amount exceeding a predetermined amount..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 72, "...output of a flow sensor to calculate said average flow rate..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 74, "...a first maximum time if said actual level has not reached said goal level or said actual level is below minimum level, determining a second minimum time if said actual level is above said goal level, and determining a variable time if said actual level has at least once reached said goal level but said actual level is between said minimum level and said goal level, said step of determining a variable time including determining a breath rate of said user from said sensed periods of inhalation by said user, determining a delivery volume comprising a desired quantity of oxygen divided by said breath rate, and determining said variable time by dividing said delivery volume by a flow rate of supplemental oxygen available..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 77, "...said desired quantity of oxygen comprises a maximum quantity when said actual level is below said minimum level..." the limitations are not

disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 78, "...a linearly changing quantity between a minimum quantity corresponding to said minimum time and a maximum quantity corresponding to said maximum time..." the limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter. In claim 80, "...said determined length of time does not exceed one-half of an inhalation time of said user..." limitations are not disclosed in the originally filed specification therefore the limitations constitute new matter.

### ***Response to Arguments***

Applicant's arguments filed 9/23/04 have been fully considered but they are not persuasive. Applicant directs the examiner to specific locations in applicant's specification to which applicant states support is provided for the claimed limitations presented, however the specific claim language used in the instant claims fails to be disclosed in the originally filed specification, while applicant may have some of the same parts of an apparatus of that of Blue (6,470,885) the specific claim language can not be found in applicant's specification nor in the Figures, applicant fails to show a flow sensor at all nor does applicant disclose the specific structure of the pressure sensor being claimed. The examiner is not convinced by applicant's submitted Appendix A Claim Chart that applicant's claim limitations are supported by applicant's originally filed specification.

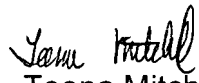
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teenā Mitchell whose telephone number is (571) 272-

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4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Teena Mitchell  
Primary Examiner  
Art Unit 3771  
June 28, 2007

  
TKM